

REMARKS

I. Status of the Application

Claims 1-13 were filed in the original Application. In the Office Action, the Examiner:

(a) provisionally rejected claims 1-13 under the judicially created doctrine of obviousness-type double patenting;

(b) rejected claims 1-13 under 35 U.S.C. § 112, first paragraph, as allegedly not enabling a person skilled in the art to use the invention;

(c) rejected claim 9 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement; and

(d) rejected claims 1-13 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,924,273 to Pierce ("Pierce").

In this response, Applicant respectfully submits the following comments and Declaration of Prior Inventorship. Claims 1-13 also remain in the Application but are not amended. Applicant respectfully submits that the following remarks and the Declaration of Prior Inventorship incorporated herein traverse or overcome the Examiner's rejections to the Application.

II. No New Matter Is Introduced by Way of Amendment

Applicant respectfully submits that as there have been no amendments to the specification, drawings, and/or claims, no new matter has been introduced to the originally filed Application.

III. **The Nonstatutory Double Patenting Rejection Of Claims 1-13 Should Be Withdrawn**

In the Office Action, the Examiner rejected claims 1-13 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,607,745 to Leneau. Applicant submits herewith a terminal disclaimer to obviate the rejection of claims 1-13 under the judicially created doctrine of obviousness-type double patenting. Applicant encloses the payment of the terminal disclaimer fee of \$130.00. For this reason, Applicant respectfully requests that the rejection of claims 1-13 under the judicially created doctrine of obviousness-type double patenting be withdrawn.

IV. **The Rejection of Claims 1-13 under 35 U.S.C. § 112, First Paragraph, as Allegedly Not Enabling one Skilled in the Art to Use the Invention is Overcome and Should be Withdrawn**

The Applicant respectfully submits that the rejection of claims 1-13 under 35 U.S.C. §112, first paragraph, as allegedly not enabling a person skilled in the art to use the invention, is overcome and should be withdrawn in view of the following comments.

The Examiner rejected claims 1-13 under 35 U.S.C. § 112, first paragraph, alleging that "the specification, while being enabling for joint disorders such as arthritis, osteoarthritis, rheumatoid arthritis, and fibromyalgia, does not reasonably provide enablement for all joint disorders." (Office Action, page 3). The Examiner further references additional specific joint disorders and alleges that the "specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims." (Office Action, page 3). Applicant respectfully submits that while it acknowledges that it did not name each and every possible joint disorder that may benefit from the ingestion of hyaluronic acid as disclosed in the Application, Applicant respectfully submits

that the number of joint disorders referenced within the Application most surely would enable one skilled in the art to use the invention commensurate in scope with these claims.

Specifically, and as acknowledged by the Examiner, Applicant disclosed several joint disorders in the Application, including the following:

- general arthritis/arthritis disorders (Paragraph 0002)
- osteoarthritis (Paragraph 0003)
- rheumatoid arthritis, both acute and chronic (Paragraph 0003)
- fibromyalgia (Paragraph 0002)
- general inflammatory skeletal and musculoskeletal conditions (Paragraph 0002)

Applicant respectfully submits that the disclosure of the aforementioned joint disorders in the Application most surely would enable one skilled in the art to use the invention commensurate in scope with these claims. "Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention." MPEP § 2164.01. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). The focus is not only on "experimentation," but is on whether or not the experimentation is "undue." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Applicant respectfully submits that no undue experimentation would be required by one skilled in the art in order to utilize the invention.

Applicant respectfully submits that while, for example, the Application does not disclose the specific joint disorder of carpal tunnel syndrome as referenced by the Examiner (Office Action, page 3), any experimentation to determine whether or not the oral ingestion of "a nutritional supplement consisting essentially of an effective amount of hyaluronic acid" (Application, claim 1) would relieve joint pain or other discomforts of carpal tunnel syndrome would not be considered "undue" experimentation. Applicant respectfully submits that such experimentation may require an oral dose of an effective amount of hyaluronic acid to a warm-blooded vertebrate with the specific joint disorder of carpal tunnel syndrome to determine whether or not the dose is effective in relieving the joint pain or other discomforts associated with that disorder. Applicant respectfully submits that at most, this would require some sort of experimentation, but that any such experimentation would not be "undue."

In addition, Applicant respectfully submits that no such experimentation may be required, as one skilled in the art may realize that one suffering from a particular joint disorder not enumerated in the Application (like carpal tunnel syndrome, for example) may benefit from the method and/or nutritional supplement disclosed in the Application. Applicant respectfully submits a Declaration from the inventor and one skilled in the art of joint disorders, Dr. Harry Leneau, affirmatively supporting the position that one skilled in the art may consider a treatment for one or more of the disclosed joint disorders (like arthritis, rheumatoid arthritis, and fibromyalgia) when attempting to treat one suffering from another joint disorder (like carpal tunnel syndrome, tendonitis, and bursitis). Accordingly, Applicant respectfully submits that the specification is properly enabling and that the rejection of claims 1-13 under 35 U.S.C. § 112, first paragraph, is overcome and should be withdrawn.

V. **The Rejection of Claim 9 under 35 U.S.C. § 112, First Paragraph, as Allegedly Failing to Comply with the Written Description Requirement is Overcome and Should be Withdrawn**

The Applicant respectfully submits that the rejection of claim 9 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement, is overcome and should be withdrawn in view of the following comments.

The Examiner rejected claim 9 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. (Office Action, page 3). The Examiner alleges that the effective amount of hyaluronic acid in claim 9 (1-6 mg) is not disclosed in the specification, acknowledging that the Application does disclose doses of 1-10 mg (Application, paragraph 0015) and 1-4 mg (Application, paragraph 0016). (Office Action, page 4).

Applicant respectfully disagrees with the Examiner's rejection of claim 9 under 35 U.S.C. §112, first paragraph, as the effective amount of hyaluronic acid claimed in claim 9 has sufficient support within the specification of the Application. Applicant respectfully submits that the Application states in Example 2 that "[e]ach patient received about 1 to about 6 mg of hyaluronic acid by oral ingestion administration of concentrate diluted into beverages or food." (Paragraph 0017). Accordingly, Applicant respectfully submits that there is sufficient support in the specification for the claimed range of 1-6 mg of hyaluronic acid in claim 9, and Applicant respectfully submits that the rejection of claim 9 under 35 U.S.C. § 112, first paragraph, is overcome and should be withdrawn.

VI. **The Rejection of Claims 1-13 under 35 U.S.C. § 102(e) as Allegedly Being Anticipated by Pierce is Overcome and Should be Withdrawn**

In the Office Action, the Examiner rejected claims 1-13 under 35 U.S.C. § 102(e) as allegedly being anticipated by Pierce. Applicant respectfully submits that the rejection of claims 1-13 is overcome and should be withdrawn because Applicant conceived, reduced to practice, and diligently completed the invention well before the priority date of Pierce. Submitted together herewith is a Declaration of Prior Inventorship in the United States (37 C.F.R. § 1.131) by the inventor for the Application, thereby eliminating Pierce as prior art to this Application. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection to claims 1-13 under 35 U.S.C. § 102(e).

Commissioner for Patents
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CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the Applicant has made a patentable contribution to the art and that this response places the Application in condition for allowance. Accordingly, favorable reconsideration and allowance of this Application is respectfully requested. In the event the Applicant has inadvertently overlooked the need for a payment of a fee or extension of time, the Applicant conditionally petitions therefor, and authorize any fee deficiency to be charged to deposit account 09-0007. When doing so, please reference the above-listed docket number.

Respectfully submitted,

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Enclosures: Transmittal Form (PTO/SB/21)
Terminal Disclaimer to Obviate a Double Patenting
Rejection Over a "Prior" Patent
Declaration of Prior Inventorship in the United States
(37 C.F.R. § 1.131)
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